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Traditional 510k - Suction Stimulator Probe

JUN 28 2011

5. 510K Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.92, the following summary of information is provided:

Applicant Information

Christine Vergely
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Neurovision Medical Products, Inc.
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Date of Summary June 28, 2011

Device Identification

Trade Name: DryTouch Suction Stimulator Probe
Common Name: Suction Stimulator Probe

Classification

Class II
Number 874.1820, Nerve Stimulator / Locator
Product code: ETN

Predicate Devices

Manufacturer: Elmed Inc.
Device Name: Frazier Suction Coagulator (part #23-5001)
510k Number: Pre-amendment device

Manufacturer: Neurovision Medical Products Inc.
Device Name: Hemostat/Stimulator Probe (SHEM-s)
510K Number: K895676

Manufacturer: Axon Systems, Inc.
Device Name: XPAK II
510K Number: K090838

Device Description

The Suction Stimulator Probe is a disposable, single use, sterile instrument that combines concurrent suction and stimulation into one device for use during tissue dissection and nerve stimulation during surgery.

The instrument consists of a stainless steel shaft, partially insulated with biocompatible PTFE and ending with a ball-tip suction. Proximal connectors attach the instrument to a nerve stimulator. A tapered type adapter attaches the device to a standard suction catheter and a finger-hole allows for adjusting the suction strength manually by the surgeon. The insulated shaft has a 2mm diameter and 2 length options of 13 or 26 cm. The ball tip feature reduces the current density of stimulation, allows stimulation along right angles, such as drill holes, and prevents bone chip clogging of the instrument.

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Intended Use

The Suction Stimulator Probe is a dedicated manual surgical instrument that allows the surgeon to clear secretions and test surgical tissue with nerve stimulation at the same time and with the same instrument. It is intended for use only by a licensed physician and in conjunction with the Neurovision SE (Nerveäna) Nerve locator Monitor System.

Technological Characteristics of Device in Relation to Predicate Devices

The Suction Stimulator Probe combines technology from several predicate devices: the **Frazier Suction Coagulator** (part #23-5001), the **Hemostat/Stimulator Probe** (SHEM-s) K895676, and the **XPAX II Nerve Stimulation Probe** (K090838).

- The Suction Stimulator Probe is substantially equivalent to the **Frazier Suction Coagulator** with an extended shaft length: the body of the Suction Stimulator Probe is a Frazier Suction Coagulator with its shaft extended from 17.7cm to 26 cm or shortened to 13 cm.

- The Suction Stimulator Probe's stimulating capability is substantially equivalent to the stimulating capability of the **Hemostat/Stimulator Probe** (SHEM-s) K895676: the device is coated with PTFE insulating material and a dedicated wire is added for connection to an approved nerve stimulator.

- The Suction Stimulator probe is substantially equivalent to the Axon Systems **XPAK II** (K090838) in that both are stimulating, dissecting instruments with biocompatible electrical insulation, which attach to a nerve stimulator for nerve stimulation during surgery.

Assessment of Performance Data Used to Justify Substantial Equivalence

Bench testing to assess performance and safety included micrometer measurement of the ball tip diameter, electrical continuity testing, and suction testing with applied air. These testing criteria were selected to test the quality of the manufacturing, the reliability of the surface area of the ball as indicating the current density of delivered stimulation, the continuity of the device as reflecting the reliability of current delivered to the tip, and finally, the gross delivery of air/suction as reflecting the suction power of the device.

Sterilization:

- EO validation is compliant with ISO 11135-1:2007.
- EO residuals analysis is compliant with ISO 10993-7:2008.
- The Sterility Assurance Level is 10^{-6}.
- Device is not labeled non-pyrogenic.

Shelf Life Testing:

- Shelf life is 1 year and was confirmed by package integrity testing compliant with ISO 11607.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neurovision Medical Products, Inc.
c/o Ms. Christine Vergely
Regulatory Manager
2225 Sperry Avenue, Suite 1000
Ventura, CA 93003

JUN 28 2011

Re: K110712
Trade/Device Name: DryTouch Suction Stimulator Probe
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: May 22, 2011
Received: May 24, 2011

Dear Ms. Vergely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Traditional 510k - Suction Stimulator Probe

Indications for Use

510(k): K110712

Device Name: Suction Stimulator Probe

Statement of Indications for Use for the Suction Stimulator Probe:

The Suction Stimulator Probe is a dedicated manual surgical instrument that allows the surgeon to clear secretions and test surgical tissue with nerve stimulation at the same time and with the same instrument. It is intended for use only by a licensed physician and in conjunction with the Neurovision SE (Nerveäna) Nerve locator Monitor System.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number k110712